



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3413-PN]

### Medicare Program; Application by Association of Diabetes Care and Education Specialists (ADCES) for Continued CMS Approval of its Diabetes Outpatient Self-Management Training Program

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice with request for comment.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from the Association of Diabetes Care and Education Specialists for continued recognition as a national accrediting organization (AO) for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 30 days after date of display in the **Federal Register**].

**ADDRESSES:** In commenting, refer to file code CMS-3413-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3413-PN,  
P.O. Box 8010,  
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3413-PN,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Shannon Freeland, (410) 786-4348.

Caroline Gallaher, (410) 786-8705.

Lillian Williams, (410) 786-8636.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been

received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

## **I. Background**

Diabetes outpatient self-management training services are defined at section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who

participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Section 1865 of the statute also permits the Secretary to use accrediting bodies to determine whether a provider entity meets Medicare regulatory quality standards, such as those established for diabetes outpatient self-management training service programs. A national AO must be approved by CMS and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for Medicare deeming authority.

Our regulations pertaining to the application procedures for diabetes outpatient self-management training AOs seeking CMS approval are set forth at § 410.142. A national accreditation organization applying for deeming authority must provide CMS with reasonable assurance that it requires the diabetes outpatient self-management training suppliers it accredits to meet the CMS' quality standards, the National Standards for Diabetes Outpatient Self-Management Education and Support (NSDSMES) standards, or an alternative set of standards that meet or exceed our requirements that have been developed by that AO and have been approved by CMS. (See § 410.144.)

Section 410.142(a) states that "CMS may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training." Therefore, diabetes outpatient self-management training AOs must be not-for-profit organizations. The national accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in § 410.144.

## **II. Approval of Accreditation Organizations**

Section 1865(a)(2) of the Act and § 410.142 require that our findings from review of a national AO's application consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found

not in compliance with the conditions or requirements; and ability to provide the Secretary with the necessary data for validation.

Section 1865(a)(3) of the Act and § 410.142(d) require that we publish, within 60 days after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Section 1865(a)(3)(A) of the Act further states, we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Association of Diabetes Care and Education Specialists' (ADCES') submission of an application requesting renewal of the CMS approval for its diabetes outpatient self-management training accreditation program. This notice also solicits public comment on whether ADCES's requirements meet or exceed the NSDSMES, which are the accreditation standards used for certification of the diabetes outpatient self-management training programs accredited by the ADCES, pursuant to § 410.144 (b).

### **III. Evaluation of Deeming Authority Request**

The ADCES submitted all the necessary materials to enable us to make a determination concerning its request for renewed CMS approval of its diabetes outpatient self-management training accreditation program. This application was determined to be complete on March 1, 2021. Under section 1865(a)(2) of the Act and our regulations at § 410.142, our review and evaluation of ADCES' application will be conducted in accordance with, but not necessarily limited to--

- The requirements and quality standards ADCES uses to accredit entities to furnish diabetes outpatient self-management training.

- The accreditation process used by ADCES to determine the following:

- ++ Frequency of accreditation.

- ++ Copies of accreditation forms, guidelines, and instructions to evaluators.

++ The accreditation review process and the accreditation status decision making process.

++ The procedures used to notify a deemed diabetes outpatient self-management training entity of deficiencies in its diabetes outpatient self-management training program and the procedures used to monitor the correction of those deficiencies.

++ The procedures used to enforce compliance with the accreditation requirements and standards.

++ Detailed information about the individuals who perform evaluations for the AO.

++ A description of the AO's data management and analysis system for its accreditation activities and decisions, including reports, tables, and other displays generated by that system.

++ A description of the AO's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

++ A description of the AO's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the AO's standards or requirements, and other actions the AO takes in response to noncompliance with its standards and requirements.

++ A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the AO, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization's application.

++ A list of all of the approved entities currently accredited to furnish diabetes outpatient self-management training and the type, category, and expiration date of the accreditation held by each of them.

++ The name and address of each person with an ownership or control interest in the AO.

++ Documentation that demonstrates ADCES' ability to furnish CMS with electronic data in CMS-compatible format.

++ A resource analysis that demonstrates that ADCES' staffing, funding, and other resources are adequate to perform the required accreditation activities.

++ A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, ADCES agrees to comply with the requirements set forth in §§410.142 through 410.146.

++ Additional information CMS requests to enable it to respond to the AO's request for CMS approval and recognition of its diabetes outpatient self-management training accreditation program.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

#### **IV. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

#### **V. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 22, 2021.

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**Lynette Wilson,**

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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